REMARKS

This Amendment responds to the office action mailed on March 09, 2006. Claims 1-36 stand rejected. These rejections are respectfully traversed. Claims 1, 10, 16, 17 and 18 are amended for clarity. This is not a limiting amendment.

Claim Rejections – 35 U.S.C. § 112

Claims 1-36 stand rejected under 35 U.S.C. § 112, second paragraph. The Assignee submits that the amendments to claims 1, 10, 16, 17 and 18 clarifies the intended meaning of the claims, and overcomes this rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 1-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Song (U.S. 5,949,999) in view of Prasad (U.S. 6,917,944). The Assignee respectfully traverses this rejection.

First, the cited references do not teach or suggest, either alone or in combination, "a computer-implemented system that integrates data from a plurality of biomedical development phases," "a database that stores data collected from the biomedical development phases," or "at least one first graphical user interface... that collects data during the first biomedical development phase...," as recited in independent claim 1. As explained in the specification, the Assignee's system, as recited in claim 1, provides a substantial benefit to the biomedical research industry because the non-standardized data technology systems typically employed in the biomedical industry are insufficient to provide the necessary information at the numerous stages of a biomedical development project, including the FDA approval stage. The cited references, however, clearly do not suggest the use of a computer-implemented system, as claimed, to

integrate data from a plurality of phases of a biomedical development project. Indeed, the cited references do not relate at all to biomedical development or the data retrieval problems associated therewith.

The office action cites to the abstract and columns 2 and 5 of the Song reference as teaching "a computer-implemented system that integrates data from a plurality of biomedical development phases" and "a database that stores data collected from the biomedical development phases." The Assignee respectfully disagrees. The Song reference describes a system for tracking changes during the development of a <u>software system</u>. Song clearly has nothing to do with the phases of a biomedical research project. The mere mention of the FDA at column 2 of the Song reference as a regulatory agency that may audit the development of safety-critical software systems does justify the conclusion of the office action that Song discloses a system for integrating data from a plurality of biomedical development phases, as recited in claim 1.

Second, the cited references do not teach or suggest, either alone or in combination, "a first metadata structure that describes the data collected during a first biomedical development phase... wherein at least a portion of the first metadata structure is configured to provide information for a subsequent biomedical development phase, [and] wherein at least a portion of the first metadata data structure contains links to another metadata structure associated with the subsequent biomedical development phase so that an audit trail may be generated," as recited in claim 1. As explained in the specification "[t]he graphical user interfaces are constructed to capture metadata whose utility may not be fully apparent until a later development phase. For example, the FDA may be concerned with whether the biomedical product was tested under certain conditions which may not have seemed relevant during the earlier development phases."

(See, specification, page 6, lines 16-20). The cited references clearly do not provide any metadata structure that addresses this issue.

The office action concludes that the Prasad reference teaches a metadata data structure as recited in claim 1. The Assignee respectfully disagrees. The Prasad reference is completely unrelated to biomedical development. Moreover, the Prasad reference clearly does not describe a metadata structure that is configured to provide information for a subsequent biomedical development phase. Rather, the cited portions of the Prasad reference describe an interface that may be used to input selection criteria for identifying data objects stored in different data repositories. The Assignee must conclude that the office action's reliance on the Prasad reference is a result of a mistaken interpretation of the claim language of claim 1, as expressed paragraph 3 of the office action with reference to the rejection under 35 U.S.C. § 112. The claim language at issued does not means "that the metadata structure is formatted or configured based upon the type of data that is obtained in the various phases of the biomedical development process," as interpreted in paragraph 3 of the office action. Rather, the metadata structure set forth in claim 1 is configured in anticipation of information that may be needed in a subsequent development phase. Claim 1 has been amended to make this distinction more clear.
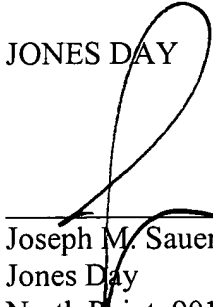
For at least these reasons, the Assignee submits that independent claim 1 is patentably distinct from the cited. Claims 2-36 each depend from claim 1, and are therefore patentable over the cited references for at least the same reasons as claim 1.

Conclusion

For the foregoing reasons, Assignees respectfully submit that claims 1-36 are in condition

for allowance. The Examiner is, therefore, respectfully requested to enter this Amendment and

pass this case to issue.

Respectfully submitted,

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